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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/566,358 | 04/13/2006 | Dominique Bourel | 065691- 0433 | 5572 |

22428 7590 07/11/2008
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| EXAMINER |
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OUSPENSKI, ILIA I

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| ART UNIT | PAPER NUMBER |
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1644

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07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/566,358 | BOUREL ET AL. | |
| | Examiner | Art Unit | |
| | ILIA OUSPENSKI | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The examiner of this application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to ILIA OUSPENSKI, Group Art Unit 1644, Technology Center 1600.

2. Claims 15 – 24 are pending.

3. Applicant's election with traverse of the Species reading on "hemolytic disease of the newborn" as the disease and on "anti-D" as the antibody in the reply filed on 04/24/2008 is acknowledged.

In the interest of compact prosecution, examination has been extended to include all the Species of the claimed invention.

4. Receipt is acknowledged of foreign priority papers (Application No. 0309440, filed in France on 07/31/2003) submitted under 35 U.S.C. 119(a)-(d), which papers are of record in the file of the instant application.

5. The information disclosure statement filed on 01/30/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*. The title is not descriptive in the use of the phrase "weak patients."

7. The specification is objected to because its layout does not conform to the provisions of 37 CFR 1.77(b). As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A “Sequence Listing” is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required “Sequence Listing” is not submitted as an electronic document on compact disc).

8. Claims 23 and 24 are objected to because the recitation “wherein the antibody is characterized in that the antibody is selected from” is in an improper Markush format. Applicant is invited to amend the claims to recite “wherein the antibody is selected from the group consisting of.” See MPEP 803.02. Appropriate correction is required.

Claims 23 and 24 are further objected to because of the following informalities: recitation of “anti-virals,” where it appears that anti-viral antibodies” have been intended. Appropriate correction is required.

9. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 15 – 24 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. Claims 15 and 23 are indefinite in the recitation of the glycan structure which “corresponds” to a biantennary type, because the degree or nature of said “correspondence” are not defined. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

B. Claims 15 and 23 are indefinite in the recitation of “short chains,” “low sialylation,” and “low fucosylation,” because the terms “short” and “low” are relative terms which render the claim indefinite. The terms are not defined by the claim, and the specification does not provide a standard for ascertaining the requisite values; therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

C. Claims 15 – 24 are indefinite in the use of exemplary claim language “in particular,” preferably,” and “for example,” recited multiple times throughout the claims. Description of examples or preferences is properly set forth in the specification rather than the claims. In the instant case, the exemplary language is deemed to lead to confusion over the intended scope of the claim. See MPEP 2173.05(d), and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949).

D. Claims 23 and 24 are indefinite in the recitation of “inhibitor-specific anti-idiotypes, for example, coagulation factors,” because the meaning of the recitation is unclear. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

11. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 15 – 24 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for methods of treating a specific disease by administering a specific corresponding antibody (such as e.g. B-cell lymphoma and anti-CD20 antibody), does not reasonably provide enablement for a method of treating a disease with an unrelated antibody (such as the great majority of disease/antibody combinations recited e.g. in claims 15 and 23), or a method of treating any disease by administering a generically recited antibody (such as recited e.g. in claim 15). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to make and use the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The instant claims are directed to methods of treating diseases by administering antibodies with an enhanced ability to induce ADCC, in particular in patients with the specified allele of CD16. One of skill in the art is aware that for such treatment to be successful, the antibody must be specific to an antigen restricted to the cell type involved in the pathogenesis of the particular disease. Antibodies specific to antigens present on other cell types would cause cytotoxicity of cells unrelated to the disease, and thus would be ineffective or harmful. Therefore, one of skill in the art would understand that although certain specific disease/antibody combinations, such as those disclosed in Table 1 at pages 17 – 18, appear to be enabled, the vast majority of possible combinations cannot be practiced as claimed without undue experimentation.

13. Claims 15 – 24 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the claimed methods, because Applicant is not in possession of the generically recited “antibody” of undefined specificity, as e.g. in claims 15 and 16; or of a generically recited “non-ubiquitous antigen” in claim 19; or of generically recited “inhibitor” or “anti-virals” in claims 23 and 24.

One of skill in the art is aware that antibodies, antigens, and inhibitors encompass vast genera of structurally and functionally diverse compounds. In the absence of a disclosure in the instant specification of sufficiently detailed, relevant identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics,

the skilled artisan cannot envision all the contemplated antibodies, antigens, and inhibitors encompassed by the breadth of the instant claims.

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

14. The following **prior art** not presently relied upon is considered pertinent to Applicant's disclosure:

Cartron et al. (Blood, 2002, 99: 754 – 758) teach that polymorphism at position 158 of the gene encoding CD16 affects the therapeutic activity of an ADCC-dependent antibody in a patient.

Beliard et al. (US Pat. Pub. No. 2003/0175969; of record) teach that antibodies produced in the YB2/0 cell line possess distinct glycan structures and increased ADCC-dependent therapeutic activity.

15. The nonstatutory **double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 15 – 24 are provisionally rejected on the ground of nonstatutory obviousness-type **double patenting** as being unpatentable over claims 1, 12, 28, and 38 of copending Application No. 10/575,333. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same or nearly the same methods of treating patients with a variant CD16 at position 158 with antibodies produced in cell line YB2/0.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 15 – 24 are directed to an invention not patentably distinct from the claims of commonly assigned Application No. 10/575,333, for the reasons set forth supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned Application No. 10/575,333, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions

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were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

18. Conclusion: no claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI, Ph.D./

Primary Examiner, Art Unit 1644

July 2, 2008